



Precision Prescribing: Attacking Avoidable Hospital, Pharmacy, and Behavioral Health Benefit Challenges

Using DNA to Improve Health Outcomes and Decrease Costs

WHY SHOULD EMPLOYERS OFFER PARALLEL PROFILE™

- IT SAVES LIVES
- IT SAVES MONEY
 - REDUCES HOSPITAL DAYS, ICU DAYS, ER VISITS, AND READMISSIONS
- INCREASES VALUE OF PHARMACY SPEND—STOPS WASTED SPENDING
- REDUCES SUICIDE
- REDUCES STRESS
- REDUCES DISABILITY, LOST TIME, AND IMPROVES PRODUCTIVITY
- INCREASES ENGAGEMENT AND EMPOWERS PLAN MEMBERS
- IMPROVES DIABETES AND OTHER CHRONIC CONDITION MANAGEMENT
- IMPROVES TREATMENT EFFECTIVENESS

What’s the # 1 thing employers have missed in pharmacy management?

Recognition of the serious financial and physical risks posed by current prescribing practices. Precision Prescribing is a breakthrough innovation that will both dramatically improve care and reduce waste and inefficiency.

Precision prescribing begins with pharmacogenomics (PGx). According to the FDA, “Pharmacogenomics (PGx) can play an important role in identifying responders and non-responders to medications, avoiding adverse events, and optimizing drug dosage.”

THE BEST DOCTORS ARE USING PGx

National Centers of excellence routinely utilize PGx to identify drugs that will work safely and effectively for each individual



But 90% of doctors overall are not using PGx.

Utilizing PGx, AI enhanced databases, sophisticated UI design, and applying a deep understanding of employer challenges and their focus on care management/cost reduction, Parallel Profile™ enables precision prescribing addressing:

- avoidable hospitalizations,
- extended length of stay,
- readmissions,
- disability, and
- wasteful ineffective pharmacy – creating a significant opportunity.
 - Stop wasting money on drugs that aren't working. Behavioral Health and Diabetes medications have high rates of ineffectiveness, but others do as well. 90% of drugs don't work for 30-50% of people¹. Typical rates of ineffectiveness for common drugs include²:
 - 38% of people taking antidepressants
 - 43% of people taking diabetes medications
 - 50% of people taking an arthritis drug
 - 70% of people taking a medication for Alzheimer's
 - Stop paying for ER and ICU when a simple adjustment in medication can prevent the problem
 - PBM savings don't net out the waste and expensive harm

It's Easy to Add Parallel Profile™ to Your Existing Benefit Program

Adding Parallel Profile to employers' existing health benefits is easy for both the employer and the covered members.

For the employers it's a simple process:

1. Parallel will identify the members who will most benefit by analyzing employer enrollment, medical and pharma claims data and then assign targets a personalized invitation with a link and a promo code. Data needed is:
 - a. Name or identification
 - b. Gender
 - c. Date of birth
 - d. Ethnicity/race
 - e. Resident state
 - f. Medications (NDC11 or RxNorm RXCUI)
 - g. Conditions (ICD10)
 - h. Email
2. Revise plan design
 - a. Coverage for Parallel Profile included for those meeting the criteria: 4+ medications, chronic condition, on problematic medication e.g. cardiac, pain, or especially behavioral health where there is such a high percentage of medication failures, as well as covering anyone scheduled to have a procedure (with or without pre-certing requirement) when anesthesia, antibiotics, cardiac drugs, and/or pain medications are anticipated.
 - b. Preferred rate (\$100 savings) for rest of population using FSA, HSA, HRA, or personal credit or debit
 - c. Lowest level copay auto exception at the pharmacy for lowest cost optimal medication
3. Parallel will share data and Integrate with other benefit vendors to maximize impact
 - a. PBM to automate inclusion of PGx results to alert pharmacist and automate exceptions/edit
 - b. EAP, DM/Chronic Care programs, Pre-cert, Care Management, and Patient Advocacy to intercept target members at most relevant time
 - c. Add to benefit site/apps

¹ *Dr. Allen Roses, formerly Duke University and Worldwide Vice President of Genetics at GlaxoSmithKline
<https://ahrp.org/glaxo-chief-our-drugs-do-not-work-on-most-patients/>
<http://news.bbc.co.uk/2/hi/health/3299945.stm>

² Pharmacogenetics', Trends in Modern Medicine 2001

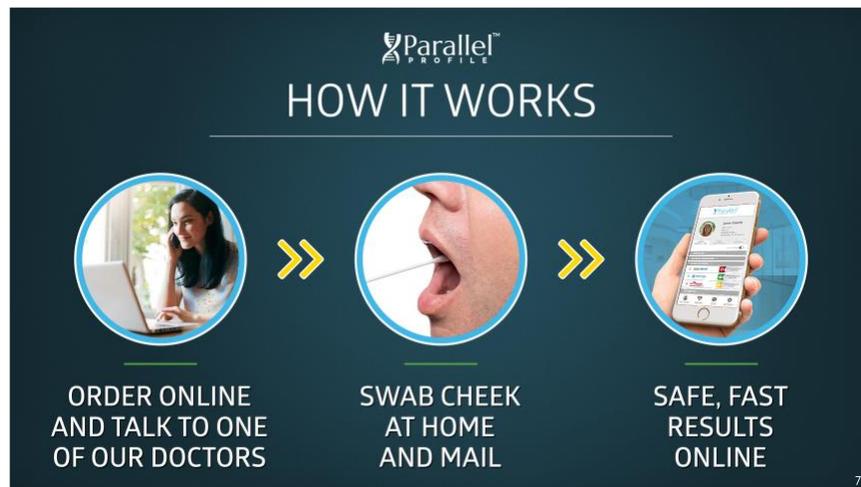
4. Parallel will promote the breakthrough benefit to members as highly significant and helpful sending them individualized invitations with a link and promo code based on their eligibility. Engagement is always a challenge, but consumers are very interested. More than 30 million Americans have already used DNA testing over the past several years (Ancestry, 23andme, National Geographic, Heritage, etc.). It's clear that people are comfortable using DNA to get valuable information. Health care genetics are equally appealing. A National Institutes of Health (NIH) funded survey done by Duke University and the University of North Carolina of 1,139 Americans, found enormous interest and willingness for PGx/DNA Medication testing:

- 73% were interested if the test could predict mild side effects
- 85% were interested if the test could predict serious side effects
- 91% were interested if the test could guide proper dosing
- **92% were interested if the test could assist in drug selection**

Parallel Profile™ does all of the above.

For the covered members it's even simpler:

Everyone will be invited to get their Parallel Profile with a unique link. For those invited targeted members, when they click the link their unique Promo Code or plan ID number will reduce their cost to zero. For the rest of the members their unique ID number or promo code will give them a deep discount and they can pay using their FSA, HSA, or personal credit card. All ordering members talk with a specially PGx trained doctor. A cheek swab kit is then mailed to their home. They swab and return the kit and their secure online results are sent to them and their designated private physician(s) within 2 weeks.



Included Conditions and Medications:

Parallel Profile™ reports on over 1,000 medications treating over 70 common conditions including:

- Depression, anxiety and other behavioral health issues
- High cholesterol
- Diabetes
- Pain
- Erectile dysfunction
- ADHD
- Cardiac conditions including clotting and platelet control
- High blood pressure
- Cancer
- Anesthesia
- Antibiotics
- Cystic fibrosis

- Acid Reflux
- Psoriasis
- Hepatitis
- Arthritis
- Kidney stones
- Gout
- Epilepsy
- Auto-immune diseases

Go to www.ParallelProfile.com/conditions for complete list

Parallel Profile™ Results Include:



The Value of Parallel Profile™

97% of people have a genetic variant that affects at least 1 of the drugs we analyze. In fact, we’ve found that most people have 12-18 variants affecting 50-240 drugs. Of the people taking a psychiatric medication, only 25% tested were on a drug in their normal response zone. 43% of people we’ve tested are currently taking a drug outside their normal response zone. A similar number don’t respond positively to Tamoxifen. A Medco-Mayo Clinic study found that 23% of people have a genetic variant relevant to Warfarin—a very common medication prescribed for 33 million people annually in order to prevent blood clots.

That's why 2.7 million people a year are admitted to a hospital with an Adverse Drug Reaction (ADR) and 128,000/year die--3 times as many as die from breast cancer. And that's not counting suicides from ineffective medication or abuse/overdoses.

The annual avoidable costs are staggering: \$221.4 billion across US with \$55.3 billion spent on patients under 65.

\$78,300	Per ADR
31 ADRS	Per 10,000 members
\$2,427,300	Per 10,000 members

Pricing Guaranteed Savings

Employer program pricing is volume based with prices ranging from \$400-\$499/Profile delivered and \$1.25 per profile owner per month in the following benefit year(s) for subscription to updates. Employer health plan members who are not eligible for a fully covered Profile get an employee discount and can buy the program with their credit/debit card, HSA, HRA or FSA.

Because it's life and death, we believe everyone needs to have access, even if their employer doesn't offer us. So, we also offer Parallel Profile™ direct to consumers. And, by establishing a retail brand and price point, we communicate value to your members. Given the challenges of adoption, we believe this is a valuable strategy. Parallel Profile™ Premium has a retail price of \$599 for results on the genetic impact for more than 1,000 medications and alternatives. There is also a discounted Family Pack for those purchasing 3 or more Parallel Profile™ Premiums.

In addition, all retail consumer members can instantly check for new medications online – anytime in the future – for an annual subscription of \$19.95 (first year subscription is free).

Key Data Points Supporting Cost Effectiveness: Guaranteed Savings

A Canadian ICANPIC study published in May/June 2017 issue of *Plans & Trusts* found:

- 56% of people tested switched at least one drug
- 16% had a dose adjustment to an existing drug
- 4% stopped a medication
- Medical savings: **ROI was 7.5:1**
- Lost time savings on psychiatric patients alone was **13:1**

In a polypharmacy study (on 2 or more drugs) published in *Neuropsychiatry Dis Treat.* 2018; 14: 225–230.

PGx was included for half the study group

- **\$3,962 savings**/PGx tested person in the first 60 days from reduced ER visits and hospital admissions

A 2013 published study (Herbild L, et al) of people taking Schizophrenia medications where half were PGx tested and half were not tested found **68% savings** in total cost of care (reduced from \$67,064 to \$20,532)

A meta-analysis study of patients taking psychiatric medications (Brown et al. 2017)

- Savings for the half who had PGx test were **\$4,000/patient/year**

Another study of patients on psychiatric medications and at least 1 other medication (Winner JG, et al. *Current Medical Research and Opinion* 2015, 1-11)

- Savings were **\$1,035.60/patient/year** on medication costs alone
- 70% of savings were from non-psych meds (why we test for all drugs-not just the psychiatric medications)

Medco-Mayo Clinic study of PGx for Warfarin found a **31% reduction in hospitalization** in first 6 months.

See Appendix (pages 7-9) for NIH published studies demonstrating the value and ROI of PGx testing

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Headquarters

Boca Raton, Florida

Founded

2016

Website

<https://paralleprofile.com/>

Genetic Lab

San Antonio, TX

Mission

We are committed to empowering consumers to protect themselves, and physicians to personalize medical treatment using genetic (PGx) testing to improve quality of care and its outcomes while reducing deaths and injuries caused by avoidable adverse reactions to common medications.

Product

An app that gives consumers and physicians instant access to both their genetic impact for over 1,000 drugs and interactions with other meds they are taking, to check their current drugs, and before taking a new drug—updated quarterly with latest CPIC findings.

Lab Credentials

- Over 120,000 genetic tests completed
- Funding received from the NIH for a “new standard of care” post-market trial of a proprietary test after passing a 6-month audit on entire lab operation of all genetic testing. 99% of labs never go through that.
- The only lab partner for the National Human Genome Center at Howard University for PGx research.
- The only U.S. lab chosen by the largest publicly traded lab company in China, CTI, <http://www.cti-cert.com/en/>
- Listed in Pharma Tech magazine as a top 10 genetic company for innovation

Leadership

CEO, Cathy Cather: 25 years in benefits consulting and enterprise deals, **leading the Health Care Strategy Practice at Towers**, and instrumental in growth acceleration **at HealthEquity, Quantum Health, Accolade, Consumer Medical, PinnacleCare, United HealthAllies, Teladoc, and Surgery Plus.**

President, Mark Kallan: 25 years in consumer products, including President and Director of two direct to consumer medical companies, Chairman and **CEO Helbros watches** selling 30+ million watches to **WalMart, QVC**, and senior management positions at 3 leading international ad agencies responsible for major accounts including **AT&T, Philips, MGM**, new product development for **Bristol Myers** and Carnegie Hall

Chief Medical Officer: Leonard Wisneski, M.D., F.A.C.P.: Professor at 3 Medical Schools including **Georgetown, George Washington, and University of Colorado**, Chairman of the Integrative Health Policy Consortium, **Chairman of NIH committees** and Medical Education Committee of American College of Physicians. Consultant to the **Veterans Administration**. Formerly CMO of **Marriott**.

Advisors

Edwin Addison: Artificial Intelligence expert **twice Entrepreneur of the Year**. Founded 6 companies and affiliations with Johns Hopkins, NC State, University of Florida and government contracts with CIA, NSA, USAF, NIH.

Todd Zander: Digital media and mobile health executive successfully built mobile and web businesses from 0-\$10M+ for **Discovery Channel, WebMD, and Doctor on Demand.**

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APPENDIX

NIH published review of multiple studies demonstrating the value and ROI of PGx testing

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6712791/>

Excerpt from link above: **Table 2 Benefit of pharmacogenetic testing on clinical outcome**

Study	Findings	Benefit	References
2019, Seven of University of Florida Health primary care clinics, 375 enrolled patients	Within the same subgroup of IM/PMs prescribed tramadol or codeine at baseline, <i>CYP2D6</i> -guided group experienced a 30% reduction in composite pain intensity compared with the usual care group.	Improved efficacy	[25]
2019, Meta-analysis of 5 randomized controlled trials (RCT), 1737 participants across five RCTs	Pharmacogenetic-guided therapy 1.71 times more likely to achieve symptoms remission relative to individuals who received usual treatment.	Improved efficacy	[26]
2018, 17 hospitals in the Netherlands, 1103 evaluable patients	Genotype-guided dosing compared with historical cohort reduced the relative risk of severe toxicity for <i>DPYD*2A</i> carriers, was safe in the single c.1679 T > G carrier, and decreased the toxicity risk in c.2846A > T carriers, although the risk was still higher for c.2846A > T carriers than wild-type patients.	Improved safety	[27]
2017, The randomized clinical Genetic Informatics Trial (GIFT), 1650 randomized patients	The numbers of individual events in the genotype-guided group vs the clinically guided group were 2 vs 8 for major bleeding (RR, 0.24; 95% CI, 0.05–1.15), 56 vs 77 for INR of 4 or greater (RR, 0.71; 95% CI, 0.51–0.99), and 33 vs 38 for venous thromboembolism (RR, 0.85; 95% CI, 0.54–1.34). Genotype-guided warfarin dosing, compared with clinically guided dosing, reduced the combined risk of major bleeding.	Improved safety	[28]
2016, AltheaDx, San Diego	Applying PGx guided recommendations across the patient population resulted in the elimination and/or replacement of one to three drugs and an estimated annual saving of US\$621 per patient.	Reduced cost	[29]
2016, Netherlands Cancer	The risk of fluoropyrimidine-induced toxicity was significantly reduced from 73% (95% CI, 58–85%) in historical	Improved safety, reduced cost	[30]

Institute, Slotervaart Hospital and Canisius Wilhelmina Hospital, 2038 patients	controls ($n = 48$) to 28% (95% CI, 10–53%) by genotype-guided dosing ($P < .001$); drug-induced death was reduced from 10% to 0%. Total treatment cost per patient was lower for screening (€2772 [\$3767]) than for non-screening (€2817 [\$3828]).		
2015,2015, The Department of Neurology, University Hospital Center Zagreb, 206 patients	Of patients in the genotype-guided group (<i>CYP2C9</i> , <i>VKORC1</i>), 97% did not have any major complications compared with the control group. Estimated total cost per patient had a nonsignificant difference between genotype-guided and control group. However, the mean cost of bleeding was estimated to have significant difference at €119.32 (95% CI: €41.95–202.69) in favor of the PGx group.	Improved safety, reduced cost	[31]
2015, AssureRx Health, Mayo Clinic, 258 patients	Gene-guided treatment raised the odds of clinical response by 2.3-fold, the guided group had a 53% greater improvement in depressive symptoms.	Improved efficacy	[32]
2015, College of Pharmacy, University of Utah, 1025 patients	Pre-emptive screening with a panel-based approach resulted in a significant reduction in hospitalizations (9.8% vs 16.1%, $P = 0.027$) and patient visits to the emergency department (4.4% vs 15.4%, $P = 0.0002$).	Reduced hospitalization, reduced cost	[33]
2015, Assurex Health, Mason, Prospectively generated cohort, Initially 2168 cases and 10,880 controls	Patients receiving PGx testing saved \$1035.60 in total medication costs over 1 year compared to the usual care cohort ($P = 0.007$). PGx testing improved adherence compared to standard of care.	Reduced cost, improved adherence	[34]
2014, Vanderbilt University, PREDICT study, 10,000 patients	Comparison of pre-emptive testing and reactive genotyping revealed that 14,656 tests would have been generated with point of care genotyping—the pre-emptive approach saves genotyping test costs by reducing the number of ordered tests by 60%.	Reduced cost	[21]
2013, The EU-PACT trial, 455 patients	In the genotype-guided group, the mean percentage of time in therapeutic range was 7.0 percentage points higher than in the control group. Significantly lower incidence of excessive anticoagulation was detected in the genotype-guided group than in the control group. Fewer adjustments in the dose of warfarin were	Improved efficacy, improved safety	[35]

2012, Vanderbilt University Medical Center, 52,942 patients	made in the genotype-guided group than in the control group. Within a 5-year window, 64.8% of individuals were exposed to at least one medication with a PGx association. Three hundred eighty-three adverse events (95% CI, 212–552) among 52,942 individuals could be prevented with an effective preemptive genotyping program.	Improved safety	[36]
2012, Mayo Clinic, 44 patients	On average, a 7.2% reduction in depressive symptoms for study subjects in the unguided treatment group was detected, compared with a 31.2% reduction in overall score for subjects in the guided group ($P = 0.002$).	Improved safety	[37]
2010, Medco Health Solutions, Mayo Clinic, 3584 patients	<i>CYP2C9</i> and <i>VKORC1</i> genotyping of warfarin recipients resulted in 31% fewer hospitalizations overall and a 43% lower risk of hospitalization for bleeding or thromboembolism.	Reduced hospitalization, reduced cost	[38]

